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PATENT



U.S. NATIONAL PHASE OF PCT/US00/11620

Serial No: 10/030,011

Filed: October 29, 2001

Applicant: John J. Bissler, et al.

Title: HEMOFILTRATION SYSTEMS AND METHOD BASED ON
MONITORED PATIENT PARAMETERS, SUPERVISORY CONTROL
OF HEMOFILTRATION, AND ADAPTIVE CONTROL OF PUMPS
(PERISTALTIC) FOR HEMOFILTRATION

Art Unit: unknown

Examiner: unknown

Atty. Dkt.: CMC\151

Cincinnati, Ohio 45202

March 25, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of candor and good faith which is imposed by Rule 56 (37 C.F.R. §1.56), the art listed on the attached form PTO-1449 is called to the attention of the U.S. Patent and Trademark Office in connection with the above identified patent application. Copies of the cited references are attached hereto. No representation is made that the cited art is the only art or that the cited art represents the best art.

The Examiner is urged to consider the cited references and to make an independent decision with respect to their materiality.

Respectfully submitted,

WOOD, HERRON & EVANS, L.L.P.



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SUBSTITUTE FORM PTO-1449
(MODIFIED)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. D. NO.
CMC/151SERIAL NO.
10/030,011INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

(37 CFR 1.98(b))

APPLICANT
John J. Bissler, et al.FILING DATE
October 29, 2001

GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER							ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A.A	4	1	3	2	6	4	4	1/2/79	Ole-Robert Kolberg	210	85	
	A.B	4	1	7	8	2	4	0	12/11/79	Harry E. Pinkerton	210	22 A	
	A.C	4	2	0	4	9	5	7	5/27/80	Ludwig Weickhardt	210	98	
	A.D	4	3	2	4	6	6	3	4/13/82	Jean C. Hirel, et al.	210	646	
	A.E	4	3	7	2	8	4	6	2/8/83	Seiji Yamagami, et al.	210	86	
	A.F	4	4	8	2	5	9	8	11/13/84	Taiji Ishii, et al.	428	195	
	A.G	4	6	0	6	8	2	6	8/19/86	Yoshihiko Sano, et al.	210	646	
	A.H	4	6	8	4	4	6	0	8/4/87	Gerald Issautier	210	90	
	A.I	4	7	2	8	4	3	3	3/1/88	Robert J. Buck, et al.	210	646	
	A.J	4	7	6	7	3	9	9	8/30/88	Stephen J. Bollish	604	5	
	A.K	4	7	6	9	1	3	2	9/6/88	Cario Patono	210	86	

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION (YES/NO)
	A.L	EP300201	23 JUN 87	Europe	A61M 1/16	A61M 1/34	Corres US pat 4,923,598
	A.M	EP373455A1	6/1990	Europe	A61M 1/34		No
	A.N	EP373455B1	9/1993	Europe	A61 1/34		Yes - claims
	A.O	EP611228	12 FEB 93	Europe	A61M 1/16	A61M 1/34	
	A.P	FR2397197	2/1979	France	A61M 1/34		No
	A.Q	WO 93/O6875	15 APR 93	International PCT	A61M 1/16		

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

A.R	1	Cobe Laboratories, Inc., <u>Centrystem 3 - Precise Ultrafiltration Control</u> , Cobe Laboratories, Inc., Lakewood, CO, 1987.
A.S	2	T.A. Depner, et al., <u>Pressure effects on roller pump blood flow during hemodialysis</u> , American Society for Artificial Internal Organs Transactions, 31:M456-M459, 1990
A.T	3	S. Dirkes., <u>How to use the new CVVH renal replacement systems</u> , American Journal of Nursing, 94(5)67-73, 1994.

EXAMINER

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	B.A	4	8	4	4	8	1	0	7/4/89	Gerard Richalley, et al.	210	646	
	B.B	4	8	8	9	6	3	5	12/26/89	Jacques Chevallet	210	646	
	B.C	4	9	2	3	5	9	8	5/8/90	Wilfried Schäl	210	87	
	B.D	4	9	8	0	0	5	4	12/25/90	Ardis R. Lavender	210	90	
	B.E	5	2	0	0	0	9	0	4/6/93	Michael G. Ford, et al.	210	739	
	B.F	5	2	1	1	8	4	9	5/18/93	Yuli Kitaevich, et al.	210	645	
	B.G	5	3	4	4	5	6	8	9/6/94	Yuli Kitaevich, et al.	210	645	
	B.H	5	5	0	3	6	2	4	4/2/96	Otfried Roeher, et al.	604	65	
	B.I	5	6	7	9	2	4	5	10/21/97	Keith Manica	210	134	
	B.J	5	7	6	2	8	0	5	6/9/98	Lori A. Truitt, et al.	210	645	
	B.K	5	7	7	6	3	4	5	7/7/98	Lori A. Truitt, et al.	210	645	

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	B.L	WO 98/50091	12 NOV 98	International PCT	A61M	1/34	
	B.M						
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	B.O						
	B.P						
	B.Q						

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	B.R	D. Driankov, et al., <u>An Introduction to Fuzzy Control</u> , Springer-Verlag, 2nd edition, 1996, Ch. 3, FKBC Design Parameters, pp. 103-144.
	B.S	E.N. Ellis, et al., <u>Use of pump-assisted hemofiltration in children with acute renal failure</u> , Pediatric Nephrology, 11:196-200, 1997.
	B.T	L.G. Forni, et al., <u>Continuous hemofiltration in the treatment of acute renal failure</u> , The New England Journal of Medicine, 336(18):1303-1309, 1997.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				APPLICANT John J. Bissler, et al.		
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U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	C.A 5 8 5 7 9 7 3	1/12/99	Qinglin Ma, et al.	600	441	
	C.B 5 9 1 0 2 5 2	6/8/99	Lori A. Truitt, et al.	210	645	
	C.C 5 9 5 6 4 6 4	9/21/99	Asad M. Madni, et al.	395	61	
	C.D 6 0 0 7 4 9 1	12/28/99	Jian Ling, et al.	600	481	
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)						
	C.R 3	Gambro AB, <u>Hemofiltration in Perspective</u> , Gambro AB, Lund, Sweden, Oct. 1989.				
	C.S 8	Gambro AB, <u>AK 10 System - Operator's manual for hemofiltration - BMM 10-1 and HFM 10-1</u> , Gambro AB, Lund, Sweden, May 1986.				
	C.T 9	G.C. Goodwin, et al., <u>Adaptive Filtering, Prediction and Control</u> , Prentice Hall, 1984, Chapter 6, pp.182-207.				
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)						
D.R	L.W. Henderson, et al., <u>Kinetics of hemodiafiltration. II. Clinical characterization of a new blood cleansing modality</u> , 1975. Journal of the American Society of Nephrology, 1997. 8(3):494-508; discussion 494-495, 497-500, Mar 1997.					
D.S	L.W. Hendersen, et al. (ed), <u>Hemofiltration</u> , Springer-Verlag, New York, 1986, pp. 83-89.					
D.T	W. Heinrichs, et al., <u>An automatic system for fluid balance in continuous hemofiltration with very high precision</u> , Intensiv-behandlung, 11 International Conference on Continuous Hemofiltration, Jahrgang 15, November 3, 1990, p. 110.					
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)	
E.R	G. Hillerström, et al., <u>Application of repetitive control to a peristaltic pump</u> , Journal of Dynamic Systems, Measurement and Control, 116:786-789, Dec 1994.
E.S	J.H. Holmes, et al., <u>Removal of fluid from the patient during hemodialysis</u> , Department of Medicine, U. of Colorado, March 1969.
E.T	International Electrotechnical Commission, <u>International Standard, Medical Electrical Equipment, Part 2: Particular requirements for safety of haemodialysis equipment</u> , International Electrotechnical Commission, Geneva, Switzerland, 1989.

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)							
	F.R	P.A. Ioannou, et al., <u>Robust Adaptive Control</u> , Prentice Hall, 1996, Ch. 1, pp. 8-12.					
	F.S	R. Johnson Jr., <u>Lecture 13: Model reference adaptive control</u> , In <u>Lectures on Adaptive Parameter Estimation</u> , Prentice Hall, 1988, pp. 111-117.					
	F.T	Y. Kitaevich, et al., <u>Development of a high-precision continuous extracorporeal hemodiafiltration system</u> , Biomedical Instrumentation & Technology, 27(2):150-156, Mar/Apr 1993.					
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	G.R	L.H. Lowrie., <u>Renal replacement therapies in pediatric multiorgan dysfunction syndrome</u> , Pediatric Nephrology (2000), 14:6-12.					
	G.S	M. Nordio, et al., <u>Projection and simulation results of an adaptive fuzzy control module for blood pressure and blood volume during hemodialysis</u> , 4535 ASAIO Journal, 40(1994) July-September, No. 3, Hagerstown MD, pp. M686-M690.					
	G.T	N.J. Ofsthun, et al., <u>Ultrafiltration and backfiltration during hemodialysis</u> , Artificial Organs, 19(11):1143-1161, 1995.					
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H.R. ✓	E.P. Paganini, <u>Acute continuous renal replacement therapy</u> , Martinus Nijhoff Publishing, 1986, pp. 91-111.
H.S. ✓	K.M. Passino, et al., <u>Fuzzy control: The basics</u> , In Fuzzy Control, Addison-Wesley, 1998, Ch. 2, pp. 22-73.
H.T. ✓	W. Pedrycz., <u>Fuzzy controllers - preliminaries and basic construction</u> , In Fuzzy Control and Fuzzy Systems, Research Studies Press, Somerset, 2nd edition, 1993, Ch. 4, pp. 22-73.

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	I.R	C. Ronco., <u>Hemofiltration and hemodiafiltration</u> , In J.P. Bosch, editor, <u>Hemodialysis: High-Efficiency Treatments</u> , Vol. 27 of <u>Contemporary Issues in Nephrology</u> , Churchill Livingstone, New York, 1993, Ch. 9, pp. 119-134.					
	I.S	M. Sagy, et al., <u>Continuous flow peritoneal dialysis as a method to treat severe anasarca in children with acute respiratory distress syndrome</u> , <u>Critical Care Medicine</u> , Vol. 27, No. 11:2532-2536, 1999.					
	I.T	J. Sands, et al., <u>Difference between delivered and prescribed blood flow in hemodialysis</u> , <u>American Society for Artificial Organs Journal</u> , 42:M717-M719, 1996.					
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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)


J.R	<input checked="" type="checkbox"/>	Sartorius GmbH, <u>Hemoprocessor 40020 Operating Instructions</u> , Sartorius GmbH, Gottengen, Germany, Sep. 1984.
J.S	<input checked="" type="checkbox"/>	J. Schaeffer, et al., <u>Long term performance of hemofilters in continuous hemofiltration</u> , Nephron, 72:155-158, 1996.
J.T	<input checked="" type="checkbox"/>	T. Terano, et al., <u>Automotive speed control</u> , In Applied Fuzzy Systems, Academic Press, Cambridge, 1989, Ch. 3, pp. 85-93.

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K.R 71	K.S. Tsakalis, et al., <u>Model reference control</u> , In Linear Time Varying Systems: Control and Adaptation, Prentice Hall, 1993, Ch. 4, pp. 90-123.
K.S 72	L.X. Wang., <u>Fuzzifiers and defuzzifiers</u> , In A Course in Fuzzy Systems and Control, Prentice Hall, 1997, Ch. 8, pp. 105-117.
K.T	

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